UNITED STATES ENVIRONMENTAL PROTECTION AGENCY WASHINGTON, DC 20460

OFFICE OF CHEMICAL
SAFETY AND POLLUTION
PREVENTION

MEMORANDUM

DATE: 1/28/2021

SUBJECT: Efficacy Review for Viper Antimicrobial Fruit & Vegetable Wash,
EPA File Symbol 70627-IR
DP Barcode: #459803
E-Submission: #52504

FROM: Sophie Nguyen
Efficacy Branch
Antimicrobials Division (7510P)
Date Signed: 1/5/2021

THRU: Thao Pham, Team Leader
Efficacy Branch
Antimicrobials Division (7510P)
Date Signed: 1/28/2021

TO: John Hebert/Terria Northern
Regulatory Management Branch I
Antimicrobials Division (7510P)

APPLICANT: Diversey, Inc.
P.O. Box 19747
Charlotte, NC 28219-0747

FORMULATION FROM LABEL:

Active Ingredient	% by wt.
Hydrogen Peroxide	6.35%
Other Ingredients	93.65%
Total	100.00%

I. BACKGROUND

Product Description (as packaged and applied): Dilutable liquid concentrate to be used to treat process water for fruit and vegetables.

Submission Type: New product registration.

Requested Action: Registrant is requesting to register the product as a water additive for pathogen reduction in fruit and vegetable wash or process water.

Documents Submitted for Consideration:

- Letters to EPA (dated July 8, 2020)
- Confidential Statement of Formula (EPA form 8570-4) dated July 7, 2020
- Data Matrix (EPA Form 8570-35) dated July 7, 2020
- Three efficacy studies (MRID Nos. 50849412 - 50849414); Statement of No Data Confidentiality Claims, Good Laboratory Practice Statement, and Quality Assurance Unit Summary were included with the studies.
- Proposed product label dated July 7, 2020.

II. USE DIRECTIONS

DIRECTIONS FOR USE:
It is a violation of Federal Law to use this product in a manner inconsistent with its labeling.
(EFFICACY CLAIMS:)
At a 1:128 dilution (1 fl. oz. of product per 1 gallon of water) (or equivalent dilution) (under Good Laboratory Practices, [GLPs]), in the presence of 1% organic soil load and 90 second contact time, this product kills the following in wash or process water for fruit and vegetables:
Bacteria:
Salmonella enterica (ATCC 10721, 6962, 13311)
Escherichia coli O157:H7 (ATCC 35150, 43890, 43895)
Listeria monocytogenes (ATCC 49594, 19114, 19116)

(FRUIT AND VEGETABLE TREATMENT INSTRUCTIONS :)
To Treat the Surfaces of Processed Fruits and Vegetables and Treatment of raw agricultural commodities and process water:
Faucet Method

1. Press the button on the dispenser and turn the button 90° clockwise to lock the button for continuous dispensing.
2. Rinse processed fruit and vegetables for 90 seconds under a continuous flow of proper strength solution.
3. Scrub or agitate processed produce as necessary to remove visible soil.
4. When finished, turn the dispenser button 90° counter-clockwise and release the button to turn off the dispenser.

Soak Tank Method

1. Fill soak tank to the desired level using the dispenser. To activate the dispenser, press the button on the dispenser and turn the button 90° clockwise to lock the button, or hold the button while the sink fills. When finished, either release the button or turn the

dispenser button 90° counter-clockwise and release the button to turn off the dispenser.
2. Submerge prepared produce for a minimum of 60 seconds.
3. Scrub or agitate processed produce as necessary to remove visible soil.
4. Drain and refill soak tank with fresh solution at least every 8 hours or when soil load becomes excessive. (Consult your Diversey representative to establish an appropriate schedule for your facility.)

When used as directed for the treatment of processed fruits and vegetables under FDA regulations, Antimicrobial Fruit and Vegetable Treatment will:
Reduce the pathogens *Escherichia coli* O157:H7, *Listeria monocytogenes* and *Salmonella enterica* on the surface of processed fruits and vegetables introduced during handling or processing.

III. BRIEF DESCRIPTION OF THE DATA

1.	**MRID**	50849412			
Exp. Start Date:		2/21/2019	**Study Completion Date**:	4/4/2019	
Study Objective		Fruit and vegetable wash additive			
Study Title		Efficacy of Antimicrobial Agents to Reduce Foodborne Pathogenic Bacteria in Processing Water for Fruit and Vegetables			
Testing Lab, Lab Study ID		Accuratus Lab Services; Project #A27061			
Test organism(s) ☒ **1** ☐ **2** ☐ **3** ☐ **4+**		*Escherichia coli* O157:H7 (ATCC 35150, 43890, 43895), 1 mL culture			
Test Method		Protocol #JD01050418.CUST.3 (*copy provided*)			
Application Method		Liquid product applied to wash water with 1% vegetable puree			
Test Substance Preparation	**Name/ID**	Viper			
	Lots ☐ **1** ☐ **2** ☒ **3**	Batch #1069D3: 6.043% H_2O_2 Batch #1069D4: 6.028% H_2O_2 Batch #1069D5: 5.984% H_2O_2			
	Preparation	1 oz./gallon of 400 ppm AOAC Synthetic Hard Water with 1% soil (3mL test substance + 384 mL of water)			
Soil load		1% concentration in water (equivalent dilutions of 5 g each of lettuce, tomato, and carrot): 15 mL soil + 1485 mL of water			
Carrier type, # per lot		Test substance diluent: 400 ppm AOAC Synthetic Hard Water with 1% soil. Three flasks of 99 mL of test substance + diluent + soil prepared per batch in triplicate			
Test conditions		**Contact time**	90 sec.	**Temp**	25°C
Neutralizer		1 mL of inoculated test substance + 9 mL neutralizer (Letheen Broth + 0.1% Sodium Thiosulfate + 0.01% catalase)			
Incubation Time and temp.		24 hours at 36°C			
Reviewer comments		Tested at LCL			

(i.e. protocol deviations and amendments, retesting, control failures, neutralizer, etc.)	

2.	**MRID**	50849413			
Exp. Start Date:		3/20/2019	**Study Completion Date**:	5/8/2019	
Study Objective		Fruit and vegetable wash additive			
Study Title		Efficacy of Antimicrobial Agents to Reduce Foodborne Pathogenic Bacteria in Processing Water for Fruit and Vegetables			
Testing Lab, Lab Study ID		Accuratus Lab Services; Project #A27275			
Test organism(s) ☒ **1** ☐ **2** ☐ **3** ☐ **4+**		*Listeria monocytogenes* (ATCC 49594, 19114, 19116), 1 mL culture			
Test Method		Protocol #JD01050418.CUST.1 (*copy provided*)			
Application Method		Liquid product applied to wash water with 1% vegetable puree			
Test Substance Preparation	**Name/ID**	Viper			
	Lots ☐ **1** ☐ **2** ☒ **3**	Batch #1069D3: 6.043% H_2O_2 Batch #1069D4: 6.028% H_2O_2 Batch #1069D5: 5.984% H_2O_2			
	Preparation	1 oz./gallon of 400 ppm AOAC Synthetic Hard Water with 1% soil (3mL test substance + 384 mL of water)			
Soil load		1% concentration in water (equivalent dilutions of 5 g each of lettuce, tomato, and carrot): 15 mL soil + 1485 mL of water			
Carrier type, # per lot		Test substance diluent: 400 ppm AOAC Synthetic Hard Water with 1% soil. Three flasks of 99 mL of test substance + diluent + soil prepared per batch in triplicate			
Test conditions		**Contact time**	90 sec.	**Temp**	25°C
Neutralizer		1 mL of inoculated test substance + 9 mL neutralizer (Letheen Broth + 0.1% Sodium Thiosulfate + 0.01% catalase)			
Incubation Time and temp.		24.75 hours at 36°C			
Reviewer comments (i.e. protocol deviations and amendments, retesting, control failures, neutralizer, etc.)		Tested at LCL			

3.	**MRID**	50849414			
Exp. Start Date:		3/20/2019	**Study Completion Date**:	5/8/2019	
Study Objective		Fruit and vegetable wash additive			
Study Title		Efficacy of Antimicrobial Agents to Reduce Foodborne Pathogenic Bacteria in Processing Water for Fruit and Vegetables			
Testing Lab, Lab Study ID		Accuratus Lab Services; Project #A27283			
Test organism(s) **☒ 1 ☐ 2 ☐ 3 ☐ 4+**		*Salmonella enterica* (ATCC 10721, 6962, 13311), 1 mL culture			
Test Method		Protocol #JD01050418.CUST.2 (*copy provided*)			
Application Method		Liquid product applied to wash water with 1% vegetable puree			
Test Substance Preparation	**Name/ID**	Viper			
	Lots **☐ 1 ☐ 2 ☒ 3**	Batch #1069D3: 6.043% H_2O_2 Batch #1069D4: 6.028% H_2O_2 Batch #1069D5: 5.984% H_2O_2			
	Preparation	1 oz./gallon of 400 ppm AOAC Synthetic Hard Water with 1% soil (3mL test substance + 384 mL of water)			
Soil load		1% concentration in water (equivalent dilutions of 5 g each of lettuce, tomato, and carrot): 15 mL soil + 1485 mL of water			
Carrier type, # per lot		Test substance diluent: 400 ppm AOAC Synthetic Hard Water with 1% soil. Three flasks of 99 mL of test substance + diluent + soil prepared per batch in triplicate			
Test conditions		**Contact time**	90 sec.	**Temp**	25°C
Neutralizer		1 mL of inoculated test substance + 9 mL neutralizer (Letheen Broth + 0.1% Sodium Thiosulfate + 0.01% catalase)			
Incubation Time and temp.		25.25 hours at 36°C			
Reviewer comments (i.e. protocol deviations and amendments, retesting, control failures, neutralizer, etc.)		Tested at LCL			

IV. RESULTS

MRID Number	Organism	Results			Carrier Population Avg. CFU/mL (Avg. Log_{10})
		Batch No.	Avg. CFU/mL (Log_{10})	Percent (Log_{10}) Reduction	
50849412	Pool 1: *Escherichia coli* O157:H7 (ATCC 35150, 43890, 43895)	**#1069D3**	<1.58 x 10^1 (<1.20)	>99.999% (>5.43)	4.27 x 10^6 (6.63)
		#1069D4	1.35 x 10^1 (1.13)	>99.999% (5.50)	
		#1069D5	2.00 x 10^1 (1.30)	>99.999% (5.33)	
50849413	Pool 2: *Listeria monocytogenes* (ATCC 49594, 19114, 19116)	**#1069D3**	<2 (<0.30)	>99.9999% (>6.43)	5.37 x 10^6 (6.73)
		#1069D4	<2 (<0.30)	>99.9999% (>6.43)	
		#1069D5	<2 (<0.30)	>99.9999% (>6.43)	
50849414	Pool 3: *Salmonella enterica* (ATCC 10721, 6962, 13311)	**#1069D3**	<2 (<0.30)	>99.9999% (>6.39)	4.90 x 10^6 (6.69)
		#1069D4	<2 (<0.30)	>99.9999% (>6.39)	
		#1069D5	<2 (<0.30)	>99.9999% (>6.39)	

V. CONCLUSIONS

MRID #	Claim	Surface Type	Application Method(s) and Dilution	Contact Time (Temp.)	Soil Load	Organism(s)	Data support tested conditions?
50849412 50849413 50849414	Fruit and vegetable wash additive	400 ppm AOAC Synthetic Hard Water + 1% soil	1 oz./gallon of 400 AOAC Synthetic Hard Water	90 sec. (25°C)	1% vegetable puree (lettuce, tomato, carrot)	*Escherichia coli* O157:H7 (ATCC 35150, 43890, 43895), *Listeria monocytogenes* (ATCC 49594, 19114, 19116), *Salmonella enterica* (ATCC 10721, 6962, 13311)	**Yes**

VI. LABEL RECOMMENDATIONS (Proposed product label dated 7/7/2020)

1. The proposed label claims that the product, Viper Antimicrobial Fruit & Vegetable Wash, is an effective treatment to reduce the following bacterial pathogens in fruit and vegetable process waters at 1:128 dilution, or 1 fl. oz. of product per 1 gallon of water, for a 90-second contact time:

   Escherichia coli O157:H7 (ATCC 35150, 43890, 43895),
   Listeria monocytogenes (ATCC 49594, 19114, 19116),
   Salmonella enterica (ATCC 10721, 6962, 13311)

   These claims are acceptable as they are supported by the submitted data. However, on page 4, under both Faucet Method and Soak Tank Method use-directions concerning the treatment of *process water* for raw/unprocessed fruits and vegetables (RACs), the solution should sit for at least 90 seconds before adding the raw fruits and vegetables. Revise 60 seconds to 90 seconds under Soak Tank Method. Refer to comment #2 below for detail on separating uses for fruits and vegetable surface and process water.

2. Throughout the label, marketing statements and directions for use for treatment (including process water) of fresh-cut and/or processed fruit and vegetable surface are under FDA jurisdiction and should be separated from EPA regulated claims for treatment of processed water for post-harvest or raw fruits and vegetables and other (RACs). The claims should be listed under different headings that clearly identify the claims as under FDA or EPA regulations.

   The Directions for Use on page 4, "To Treat the Surfaces of Processed Fruits and Vegetables and Treatment of raw agricultural commodities and process water" should be separated accordingly with their appropriate directions for use for treatment of raw agricultural commodities (RACs), process water for RACs, and treatment of processed or fresh-cut fruit and vegetables and their FDA/EPA indication. Since efficacy data were not submitted for raw or unprocessed fruits and vegetables, the directions for use should specify effectiveness against nonpathogenic bacteria only for this use. See comment #3.

3. Throughout the label, public health claim is limited to processing water for raw or unprocessed fruits and vegetables (RACs). Remove any references to public health related claims on raw or post-harvest fruit and vegetable surface (RACs). The series of marketing claims on page 2 that reference the use of the product on fruit and vegetable surface should remove any public health related terms and should only be limited to non-public health use.

4. Throughout the label, registrant should remove the dispensing systems to produce the solutions or provide addition information on these systems for the agency to verify that the systems can produce an appropriate effective concentration of active ingredient in the water. The test solution was manually mixed together using indicated amounts of water and product for testing, and the directions for use should reflect this. The first steps under Faucet Method and Soak Tank Method should be revised at this time.

5. On page 1,

a. "Water Additive for Pathogen Reduction…" should be changed to "Water Additive for Bacterial Pathogen Reduction…"
b. "Reduces Bacterial Pathogens on Processed Fruit and Vegetable Surfaces" should be qualified to reference nonpathogenic bacteria. Public health claim is limited to processing water for raw or unprocessed fruits and vegetables.

6. On page 2,
    a. Remove claims referencing that the product can "sanitize", such as "Features the cleaning, sanitizing and oxidizing power of AHP," "Formulated to deliver cleaned and sanitized produce in 90 seconds," "Next-generation fruit and vegetable sanitizer based on proprietary AHP® Technology," and "Broad-spectrum fruit and vegetable sanitizer." The product was tested as a treatment of process water to achieve bacterial reduction in the water. "Sanitize" is misleading and implies heightened efficacy.
    b. Remove or revise "Powered by AHP Technology" to specify this has a cleaning claim as "powered" implies heightened efficacy.
    c. The claim "Reduced microbial contamination of processed produce when used as directed" to "Reduced microbial contamination of processed produce treated in the same wash or process water."
    d. Remove "Unique organic soil load tolerance allows solutions to be used for up to 8 hours" and other references to the solution being changed every 8 hours for process water. Efficacy data did not substantiate this solution stability claim. Solution should be replaced when visibly soiled.
    e. The statement, "(This product)(Product name) can be applied to the following types of fresh fruits and vegetables, post-harvest", and the subsequent items listed imply that the product is mainly intended to be use on fruit and vegetable surfaces for public health purposes, and not process water for raw/unprocessed fruits and vegetables. This statement should be clarified further with "to control nonpathogenic bacteria" on these fruit and vegetable surfaces or indicate that this section of items belongs under FDA regulations for processed fruits and vegetables (non-RACs).

7. On page 4, the directions for use for treatment of process water for raw fruits and vegetables should instruct users to replace the water when process water becomes visibly soiled, not every 8 hours or "when soil load becomes excessive". The product was tested with only 1% organic soil; therefore, it is important that the water is replaced with a fresh solution when visibly soiled.